

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

THIS DOCUMENT RELATES TO:

Track Three Cases

MDL No. 2804

Case No. 1:17-md-2804

Judge Dan Aaron Polster

**REPLY IN SUPPORT OF DEFENDANTS'
MOTION TO EXCLUDE CERTAIN OPINIONS AND
TESTIMONY OF DR. KATHERINE KEYES**

REPLY EXHIBIT 2

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK: PART 48

-----x

IN RE: OPIOID LITIGATION

INDEX NO.: 400000/2017

-----x

September 10, 2020
Central Islip, New York

MINUTES OF FRYE HEARING
(Testimony of Dr. Keyes)

B E F O R E: HON. JERRY GARGUILO
 Supreme Court Justice

A P P E A R A N C E S:

SIMMONS HANLY CONROY, LLC
Attorneys for Suffolk County
112 Madison Avenue
New York, New York 10016
BY: JAYNE CONROY, ESQ.
THOMAS I. SHERIDAN, III, ESQ.
(212) 784-6401
jconroy@simmonsfirm.com
tsheridan@simmonsfirm.com

NAPOLI SHKOLNIK, PLLC
Attorneys for Nassau County
400 Broadhollow Road, Suite 305
Melville, New York 11747
BY: SALVATORE C. BADALA, ESQ.
(212) 397-1000
sbadala@napolilaw.com

Frye Hearing - Dr. Keyes

55

Q. In your work on this case, did you also review rates of prescribing of prescription opioids?

A Yes.

Q. And did you do that in -- in reviewing studies that analyzed that sort of data?

A Yes.

Q. Now, in this last section of this examination, I'd like to discuss how you applied your methodology in reaching your opinions.

THE COURT: Doctor, is this your methodology or the Bradford Hill methodology that you applied?

THE WITNESS: I would say it fits into both. You know, the Bradford Hill methodology is sort of a larger set of criteria to use when looking at a body of literature, but, you know, the reliability of the underlying data is one of those factors. And so --

THE COURT: Did I hear correctly, you indicated that you applied six of the criteria of the Bradford Hill methodology?

THE WITNESS: Yes.

THE COURT: Is there nine?

Frye Hearing - Dr. Keyes

56

THE WITNESS: There are nine.

BY MR. REISMAN:

Q. Would it be fair to say that you applied all of the factors, but the six that we've just discussed are the most important factors for purposes of explaining your methodology today?

MR. SCHMIDT: I'll object to his feeding testimony to the witness, leading.

THE COURT: Just do me a favor. Take the mask off for a second. What's the objection?

MR. SCHMIDT: Sorry. I will object to that one as leading because he's feeding testimony to the witness.

THE COURT: Rephrase the question. I'm not going to consider the answer. Rephrase the question, and then I'll consider the answer.

BY MR. REISMAN:

Q. Dr. Keyes, in your methodology in this case, did you apply all of the Bradford Hill factors?

A Generally, if I can give an example, I think it would be helpful.

Frye Hearing - Dr. Keyes

57

THE COURT: Go ahead. Give me an example.

THE WITNESS: So another Bradford Hill criteria, for example, is analogy. An analogy is, you know, not necessarily the, you know, whether the evidence is consistent with other associations in the literature that aren't germane to the one that you're considering. And I used analogy in my report.

I just didn't consider it to be among the most, you know, kind of important and compelling factors that drove my opinions, but certainly there are in my report analogies in other, in other literatures, and that would be a Bradford Hill criteria. So that's an example.

THE COURT: Next question.

BY MR. REISMAN:

Q. Did you use the name Bradford Hill? Does it appear in your report anywhere?

A No.

Q. But you did use the principles, the factors that Bradford Hill described in your report;

1 is that right?

2 A That's right.

3 Q. Now, we're going to move on in this last
4 section to talking about your opinions and how you
5 got from your methodology to your opinions. Does
6 this slide summarize your opinions at a high level
7 in this case, the opinions relating to causation?
8

9 A Yes.

10 THE COURT: Do you have a copy of that
11 slide on paper?

12 MR. REISMAN: We can make one.

13 THE COURT: I'll move it. We can see it
14 this way. Thank you.

15 BY MR. REISMAN:

16 Q. So the first one, Dr. Keyes, is use of
17 prescription opioids increases the risk of opioid
18 use disorder and abuse of illicit opioids such as
19 heroin and fentanyl; is that right?

20 A Yes.

21 Q. The second is the increased supply of
22 prescription opioids since the 1990s led to an
23 increase in rates of opioid use disorder, opioid
24 overdose deaths, and other harms. Did I read that
25 correctly?

1 a term, Bradford Hill, that you never once mention
2 in your report; is that correct?

3 A That's correct.

4 Q. You don't lay out in your report,
5 according to the nine factors of Bradford Hill and
6 how you believe your opinions track against those
7 nine factors, correct?

8 A Correct.

9 Q. And you certainly don't do that if you
10 recall Slide 14 of your presentation, that's where
11 you have the three individual opinions. You
12 certainly don't do that for those three individual
13 opinions. Say, for this opinion, here's how factor
14 one is met, here's how factor 2 is met, here's how
15 coherence is met. Here's how analysis of alternate
16 causes is met, correct? You don't do that?

17 A That's right.

18 Q. There's no mention at all in your
19 report, for example, of something like biological
20 plausibility, correct?

21 A Those words may not be in the report.

22 Q. Now, you do set forth your methodology
23 in your report, correct?

24 A Yes.

Frye Hearing - Dr. Keyes

115

Q. Do you have it handy?

A Yes.

Q. If you look at page 11 of your report, I believe there is a two- or three-page discussion of your methodology for the review of the evidence, correct?

A Yes.

Q. And there's no mention of Bradford Hill in there, correct?

A Not that name.

Q. There's no walk through of Bradford Hill factors one by one in there, is there? Yes or no.

A Not of the Hill factors.

Q. Okay. And you talked about published articles you have on prescription opioids. You've never published an article on prescription opioids that contains one of the three opinions that you stated on Slide 14 that you were shown with Plaintiffs' counsel. You've never published an article setting forth one of those three opinions and specifically invoking Bradford Hill to analyze those opinions, correct?

A I mean, those are two questions, right? The first is --

Frye Hearing - Dr. Keyes

116

1
2 Q. It's a two-part question. Have you
3 published the opinions that you've given us in court
4 in an article that specifically discusses the
5 Bradford Hill factors or even references the
6 Bradford Hill criteria? Yes or no.

7 A The word Bradford Hill specifically?

8 Q. Yes.

9 A Not the word Bradford Hill specifically.

10 Q. Or that walks through each factor one at
11 a time?

12 A The discussion sections of the paper is
13 generally in epidemiology cohered to the types of
14 factors that Bradford Hill outlined in.

15 Q. Can you points me to a paper you
16 published where you give one of the opinions on
17 causation in this case and specifically walk through
18 the various Bradford Hill factors to support that
19 opinion? Yes or no.

20 A No, not at the time.

21 Q. Now, I'd like to turn now to the
22 substance and how that tracks your methodology, and
23 I want to start first with your opinion on supply.
24 I want to talk about the why of supply.

25 Are you aware that the DEA, the Drug